

### III. Remarks

Claims 1-3, 7, 9, 11, 12, 16, 18-20, 22, 25, and 27 are pending and rejected. Specification paragraphs [0036] and [0045] have been amended, and claims 1, 20, and 25 have been amended. With the amendments and remarks provided herewith, the Applicants respectfully request reconsideration and a withdrawal of all objections and rejections to the pending claims.

#### *Objections to the Specification*

Responsive to the objections to the specification based on informalities in paragraph [0036] of the present application, paragraph [0036] has been amended on line 2 to read "cannula housing or housing 10" and line 3 to read "a housing member or member 12." Support for these amendments may be found in paragraphs [0036] and [0037] of the present application as originally filed. Thus, no new matter has been added.

Responsive to the objection to paragraph [0045], paragraph [0045] has been amended on line 2 to recite "H<sub>2</sub>" rather than Hid. Support for these amendments may be found in paragraphs [0039], [0041], [0047], [0051], [0054], [0060], and [0065] of the present application as originally filed. Thus, no new matter has been added.

#### *Objections to the Claims*

Claims 1-3, 7, 9, 11-12, 16, 18-20, 22, 25, and 27 have been objected to based on particular informalities. Responsive to the objection of claims 1, 19, and 27 on whether an "and" should be inserted before "defining," the Applicants assert that no further amendments are necessary, e.g. "and," to any of claims 1, 19, and 27. Thus, no amendments to the claims have been made regarding this objection. It is asserted that the last clause of each of claims 1, 19, and 27 is correctly recited.

Responsive to the objection of claim 27 regarding "a catheter," claim 27 has been amended in the second to the last line to recite "a catheter" as suggested by the Examiner.

*Claim Rejections – 35 U.S.C. § 112*

It is to be noted that the Detailed Action was not clear as to which portions of the independent claims that are rejected. See paragraph 4 on pages 4-7 of the Detailed Action. Thus, the Applicants have addressed each term underlined in paragraph 4 (pages 4-7) of the Detailed Action.

Responsive to the rejections of claims 1-3, 7, 9, 11-12, 16, 18-20, 22, 25, and 27 under 35 U.S.C. § 112, first paragraph, the Applicants assert that the claims contain subject matter which is described in the specification of the present application as filed in such a way as to reasonably convey to one skilled to which it pertains. For example, claim 1 recites a "housing member" rather than a housing. Support for such terminology may be found in paragraph [0036] of the present application. As mentioned in paragraph [0036], the valve body 1 is received into recess 18 and is sandwiched between sections of wall 19 and cap 17 and abuts "housing member 12." Moreover, housing member 12 is clearly shown in the drawings as originally filed, particularly in figures 1, 2, and 16 of the drawing.

Moreover, responsive to the rejection of claim 1 reciting "a valve body to be received in the recess and mounted to the housing member in the passage," the subject matter complies with the written description under 35 U.S.C. § 112 as described in paragraphs [0036] and [0045] of the specification and depicted in Figures 1-2 and 16 in the drawings of the present application. For example, paragraphs [0036] and [0045] state that "[v]alve body 1 is received into recess 18 and is sandwiched between sections of wall 19 in cap 17 and abuts housing member 12." Moreover, paragraphs [0006] and [0010] both state that a "valve body is mounted in the passage." Furthermore, Applicants refer the Examiner to Figures 1-2 and 16, each of which shows the valve body 1 to be received in the recess 18 of the cap 17 and mounted to the housing member 12 in the passage.

As for the rejection of claim 1 regarding the height dimension and the width dimension being unequal to the recess dimensions (see pages 4 and 5 of the Detailed Action), the Applicants assert that the language in each of claims 1, 19, and 27 complies with the written description under 35 U.S.C. § 112. For example, paragraph [0041] of the present application clearly states that the valve body 1

results in it having a height dimension  $H_2$  which is greater than its width dimension  $W_2$ . Paragraph [0041] then further refers to figures 2 and 8, depicting valve body 1 both before and after it has been compressed in order to be positioned in recess 18 of housing 10. Moreover, paragraph [0041] further describes that "[b]efore being compressed, valve body 1 has a height dimension  $H_2$  which is greater than (unequal) height dimension  $H_1$  of recess 18 as shown in fig. 2." Paragraph [0041] also mentions that the valve body is configured to be compressed along the height dimension when the valve body is received by the recess as recited in the claimed invention. "Planar portions 4 allow the valve body 1 to expand in its width dimension without interacting with the recess when it is compressed and received within the recess 18." See Paragraph [0041].

Responsive to the rejection of claim 1 regarding the valve body having "2 opposing planar faces," Applicants assert that the specification complies with the written description requirement under 35 U.S.C. § 112. Particularly, the Applicants refer the Examiner to specification paragraphs [0007], [0039], [0045], and [0054] of the present application. For example, in paragraph [0007], the valve body has "2 opposing planar surfaces and a peripheral edge that separates the faces." Moreover, "[v]alve body 1 includes a pair of opposing faces 6 which are separated by a peripheral edge 5." See specification, paragraph [0039]. Furthermore, paragraphs [0045] and [0054] provide additional language, further complying with the written description requirement under 35 U.S.C. § 112. The Applicants further refer the Examiner to the drawings of the present application, e.g., Figures 1, 2, 6, 7, 14, 15, 16, 18, and 19, each of which depicts the valve body having 2 opposing planar faces as recited in the claimed invention.

Responsive to the rejection of the claimed language regarding the "valve body is unstressed before being received in the recess of the housing," the Applicants again assert that the specification as originally filed complies with the written description requirement under 35 U.S.C. § 112. The Applicants refer the Examiner to paragraph [0045] and Figure 1 of the present application. Paragraph [0045] describes that the valve body is compressed in the direction of arrows 8 in order to be "received in the recess 18." Figures 1, 2, and 16 further show such

claimed limitation. Further discussion of such claimed limitation may be found in paragraph [0010] of the present application.

Responsive to the rejection of the claimed language regarding a "first slit that opens in one of the planar faces and a second slit that opens in the other planar face," the Applicants again assert that the specification of the present application complies with written description requirement under 35 U.S.C. § 112. The Applicants refer the Examiner to paragraph [0007], and Figures 7 and 9 of the present application. For example, paragraph [0007] describes that a "first slit opens in one of the planar faces and a second slit opens in the other planar face." Moreover, Figures 7 and 9 provide further support that the claimed language is in compliance with the written description requirement.

Responsive to the rejection of the claimed language regarding the valve body has "a first planar dimension across the first or second planar face through the center of the valve body and a second planar dimension across the first or second planar face," the Applicants assert that the specification of the present application complies with the written description requirement under 35 U.S.C. § 112. The Applicants refer the Examiner to specification paragraphs [0007], [0010], [0037], [0040], [0041], and [0042] of the present application. For example, paragraph [0010] states that the valve body has "a first planar dimension" and paragraph [0008] describes a first planar face and a second planar face as recited in the claims. Furthermore, the drawings of the present application further supports compliance with the written description requirement under 35 U.S.C. § 112.

Responsive to the claim limitation of a "cap having a circular recess," (as part of the specification) claims 7 and 16 as originally filed recites that the recess is a circular recess with a circular cross section. Thus, under 35 U.S.C. § 112, the present application is in compliance with the written description requirement.

Responsive to the rejection of the claimed language regarding a "valve body having an oval shape before being received in the recess while the valve body is unstressed," Applicants again assert that the present application complies with the written description requirement under 35 U.S.C. § 112. The Applicants refer the Examiner to paragraphs [0010] and [0063]. For example, paragraph [0010]

describes that "the peripheral edge can have an oval shape before the valve body is mounted in the passage."

Responsive to the rejection of the claim language regarding "specifically located rings," the Applicants assert that the present application complies with the written description requirement under 35 U.S.C. § 112. The Applicants refer the Examiner to paragraphs [0011], [0044], [0045], [0046], [0048], [0049], and [0050]. For example, paragraph [0011] describes that the opening is provided with "an internal ring positioned within the valve body between the second planar face and the intersection between the slit plane and the opening." Paragraph [0044], [0045], [0046], [0048], [0049], and [0050] provide further support to compliance with the written description requirement under 35 U.S.C. § 112.

Responsive to the rejections of claims 20, 22, 25, and 27 under 35 U.S.C. § 112, second paragraph, claims 20, 25, and 27 have been amended to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Specifically, claim 20 has been amended to recite that the "cap has a recess with a height dimension." Support for the amendment may be found throughout the specification, particularly paragraphs [0039], [0041], [0045], [0051], [0054], and [0065]. Thus, no new matter has been added. Moreover, claim 25 has been amended to recite that the valve body includes an external raised ring on the second planar "face." Support for this amendment may be found on paragraph [0008] of the present application. Thus, no new matter has been added. Furthermore, claim 27 has been amended in the second to the last line to recite that "producing a closing force on the slits" to now particularly point out and distinctly claim the subject matter which the Applicants regard as the invention. No new matter has been added.

*Claim Rejections – 35 U.S.C. § 103*

Responsive to the rejections of claims 1-3, 7, 9, 11-12, 16, 18, and 27 under 35 U.S.C. § 103 as being unpatentable over the combinations of Matsumoto et al. '665 (*Matsumoto*) with each of Dudar et al. '394 (*Dudar*), Picha et al. '654 (*Picha*), Muto '548 (*Muto*), and Spademan '127 (*Spademan*), each combination mentioned above does not teach each and every element of the claimed invention or is

improper to combine. For example, claim 27 (and similarly claim 1) recites that "the width dimension being less than the second height dimension when the valve body is unstressed . . . the valve body configured to be compressed along the second height dimension when the valve body is received by the recess." Each of the combinations of *Matsumoto* and *Dudar*, *Matsumoto* and *Picha*, and *Matsumoto* and *Muto* fails to teach such claimed limitation of claim 27 (and claim 1). First, *Matsumoto* and each of the secondary references combined therewith do not describe the valve body being compressed along the second height dimension when the valve body is received by the recess.

Contrarily, in *Matsumoto*, the valve body is clamped between the main body and the cap and, as a result, the valve body is compressed along the thickness rather than the second height dimension (or height). Therefore, *Matsumoto* does not disclose a valve body configured to be compressed along the height dimension when received by the recess. In fact, more than likely, the height dimension of the valve body in *Matsumoto* would be expanded rather than compressed when the valve body thickness is compressed. This is contrary to the claimed invention, i.e., "the valve body configured to be compressed along the second height dimension when the valve body is received by the recess." Furthermore, none of the secondary references mentioned above teaches that "the width dimension being less than the second height dimension when the valve body is unstressed . . . the valve body configured to be compressed along the second height dimension when the valve body is received by the recess."

As for the combination of *Matsumoto* and *Spademan*, the combination is improper. As mentioned above, *Matsumoto* teaches the valve body being clamped between the main body and the cap, thereby compressing the thickness rather than the height dimension of the valve body. More than likely, the height dimension of the valve body in *Matsumoto* would be expanded rather than compressed when the valve body thickness is compressed. On the other hand, *Spademan* teaches away from *Matsumoto*, i.e., *Spademan* solves a similar sealing problem by generating a first force of a given magnitude generally along a first axis a and a second force of different magnitude along a second axis b in a plane substantially normal to the thickness of member 10. See *Spademan*, col. 3, ll. 17-23; see also Figures 4d-7d.

Moreover, the *Matsumoto* and *Spademan* combination fails to teach the valve body having "a first slit formed on one of the faces and a second slit formed on the other face, each slit formed through a portion of the valve body and intersecting with the slit within the valve body" as recited in claim 27.

As for claim 1, claim 1 has been amended to recite that the valve body is configured to be "compressed only along the height dimension" when the valve body is received by the recess (emphasis added). None of the combinations mentioned above teach such limitation.

As for claims 2-3, 7, 9, 11, 12, 16, and 18, these claims depend generally on independent claim 1. Thus, claims 2, 3, 7, 9, 11, 12, 16, 18, 20, 22, and 25 are allowable for the reasons provided above.

Responsive to the rejections of claims 19, 20, 22, and 25 under 35 U.S.C. § 103 as being unpatentable over the combination of *Behnke et al. '034 (Behnke)* and *Thomas et al. '463 (Thomas)*, the combination fails to teach each and every element as recited in the present application as claimed. For example, claim 19 recites a medical instrument comprising a valve body having a height dimension that is greater than the width dimension when the valve body is unstressed. Neither of the references discusses a valve body with a height dimension that is greater than the width dimension as recited in claim 19 of the present application. Although the Examiner refers to *Behnke* as having such claim limitation, it is unclear to where in *Behnke* the teachings are found. For example, the Examiner refers to reference numerals 121 and 38 as the height and width dimensions, respectively. However, there is no reference numeral 121 found in *Behnke*, and reference numeral 38 is "a generally constant diameter cylindrical portion 36 extending from the frustoconical portion 36 to the outside end 26 of the septum 22." *Behnke*, col. 3, ll. 26-28. Neither of the references in the combination discloses a valve body compressed along the height dimension when received within the recess as recited in claim 19. Hence, neither *Behnke* nor *Thomas*, nor combination thereof, teaches each and every element of the claimed invention.

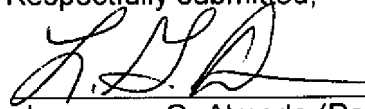
Furthermore, on page 13 of the detailed action, the Examiner incorrectly describes that the "height dimension and the width dimension defining a plane

parallel to the first and second faces and perpendicular to the slits, the height and width dimensions being unequal to the recess dimensions," is not accurate. Nowhere in either of the cited references is there a teaching that the height and width dimensions are unequal to the recess dimensions as recited in claim 19.

As for dependant claims 20, 22, and 25, these claims generally depend from claim 19. Thus, claims 20, 22, and 25 are allowable for the reasons provided above.

Thus, claims 1-3, 7, 9, 11, 12, 16, 18-20, 22, 25, and 27 are in a condition for allowance and such action is earnestly solicited.

Respectfully submitted,



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Date